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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,743

05/26/2005

Hiroyuki Osada

1261-0156PUS1

6909

2292 7590 02/26/2009
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EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT

PAPER NUMBER

1626

NOTIFICATION DATE

DELIVERY MODE

02/26/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<i>Office Action Summary</i>	Application No.	Applicant(s)	
	10/516,743	OSADA ET AL.	
	Examiner	Art Unit	
	Susannah Chung	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2008.
2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,5-8 and 10-12 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 5, 7, and 10-12 is/are allowed.
6) ☒ Claim(s) 3,6 and 8 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 3, 5-8 and 10-12 are pending in the instant application. Claims 1-2, 4, 9, and 13 are canceled.

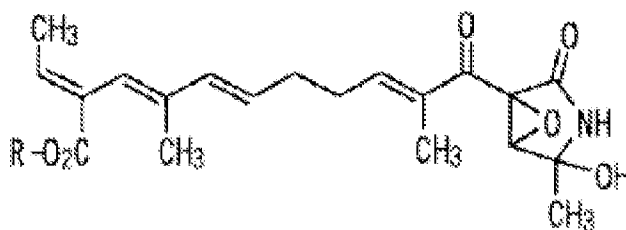
Response to Non-Final Office Action

Acknowledgment is made of applicant's response and amendment of the claims filed on 11/21/2008.

Claim 13 was rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims, for the reasons describe below. This claim has been canceled and this rejection is withdrawn.

Claim 6 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The amendment to the claim is acknowledged and this rejection is withdrawn.

Claims 3, 6 and 8 were rejected under 35 U.S.C. 103(a) as being anticipated by Hayashi et al., Chem. Lett., Vol. 27(4), 1998, p. 313-314, especially page 313 and Kuramochi et al., Tet. Lett., Vol. 40, 1999, 7371-7374, especially page 7371. Applicants submitted a declaration on 4/27/2007 from Dr. Kakeya, wherein a side by side comparison was done between the instantly



claimed compound of formula (I),
, wherein
R is tert-butyl and the prior art compound, wherein R is methyl (i.e. Epolactaene). The

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declaration shows a 5 fold efficacy of the instantly claimed compound over the prior art compound in inhibiting the growth of neuroblastoma cells. Applicants state that this is important because administering “lower drug dosage to a patient to obtain the same effect drastically reduces any potential side-effects.” The declaration and remarks have been carefully considered, but are not found persuasive to overcome the obviousness rejection. First, Applicants compound and the prior art compounds are used for the same purpose, i.e. inhibiting the growth of neuroblastoma cells. Second, a five fold difference is not an unexpected difference. For example, the courts have stated that a 50-fold difference is unobvious (See In re Soni, 54 F.3d 746, 34 USPQ2d 1684 (Fed. Cir. 1995).) In addition, Applicants do not state that the 5-fold difference would be unpredictable to one of ordinary skill in the art.

Therefore, it would have been predictable to make these compounds to one of ordinary skill in the anti-tumor art. Applicants compound does not differ dramatically with the prior art compound. The instantly claimed compound is a complex structure and the only difference is the R moiety at the end of the compound on the other end of the more active part of the compound, i.e. the heterocyclic ring or lactam ring. The core structure is a complicated heterocyclic ring with a substituted alkyl/alkenyl chain off the ring. Applicants compound is considered a homolog of the prior art compound, i.e. adding successive carbon moieties to an already existing alkyl group. Applicants compound could also be considered obvious under In re Wood wherein methyl was substituted for hydrogen. (Hydrogen and methyl are deemed obvious variants. In re Wood, 199 USPQ 137.)

It is well known in the art that the most active part of epolactaene is the lactam ring. In Nagumo, et al. it discusses that the unique lactam moiety is critical to the growth inhibition of

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human cancer cells. (See Nagumo et al., Bio & Med Chem Lett, 14(17), 2004, pp 4425-4429, see page 11 of 12 last full paragraph of Applicants enclosed copy.) Therefore, it would have been predictable to one of ordinary skill in the art to substitute various moieties such as a homolog at the terminal end away from the lactam to modify epolactaene without altering the main binding site of the compound.

When we consider the properties of the instantly claimed compound to the properties of the prior art compounds there is nothing unremarkable about the instantly claimed compounds that one of ordinary skill in the art would not have been able to predict.

The Office will consider more specific information with regard to the instantly claimed compounds.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Golam M. M. Shameem/
Primary Examiner, Art Unit 1626

Susannah Chung, 2/10/2009